

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF MICHIGAN  
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

Case No. 1:22-cv-441

ABBOTT LABORATORIES, a corporation  
doing business as ABBOTT NUTRITION,  
and KEENAN S. GALE, TJ HATHAWAY,  
and LORI J. RANDALL, individuals,

Hon. Hala Y. Jarbou

Defendants.

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**AGREED ORDER AMENDING CONSENT DECREE**

Having before it the Parties' Joint Agreed Motion to Amend the Consent Decree of Permanent Injunction entered on May 16, 2022 (the "Decree," ECF No. 8), the Court finds as follows:

1. The Decree defines "Inventory Products" to "refer only to the non-recalled powdered finished products manufactured at the Sturgis Facility and in Defendants' possession, custody, or control as of March 18, 2022, the close of FDA's inspection at Defendants' facilities located at 901 North Centerville Road, Sturgis, Michigan 490901." Decree ¶ 7(E) (ECF No. 8, PageID.64).

2. The Decree also defines "Specialty Operations" as "Defendants' manufacture, processing, preparing, packing, labeling, holding, and/or distribution at or from the Sturgis Facility of any article of food that is: (1) Any powdered infant formula covered by 21 U.S.C. § 350a(h)(1); or (2) Any powdered product for non-infants (older than 12 months of age) that serves similar nutritional purposes as any formulation of powdered infant formula covered by 21 U.S.C. § 350a(h)(1)." Decree ¶ 7(G) (ECF No. 8, PageID.64-65).

3. The Parties have agreed on the following amended definition of “Specialty Operations”:

“Specialty Operations” shall refer to Defendants’ manufacture, processing, preparing, packing, labeling, holding, and/or distribution at or from the Sturgis Facility of any article of food that is:

(1) Any powdered infant formula covered by 21 U.S.C. § 350a(h)(1); or

(2) Any powdered product for non-infants (older than 12 months of age) that serves similar nutritional purposes as any formulation of powdered infant formula covered by 21 U.S.C. § 350a(h)(1),

*except that such food shall not include Inventory Products defined in paragraph 7(E).*

THEREFORE, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. The Joint Motion is GRANTED for due cause shown.

2. Paragraph 7(G) of the Decree is amended and modified to read as follows:

“Specialty Operations” shall refer to Defendants’ manufacture, processing, preparing, packing, labeling, holding, and/or distribution at or from the Sturgis Facility of any article of food that is:

(1) Any powdered infant formula covered by 21 U.S.C. § 350a(h)(1); or

(2) Any powdered product for non-infants (older than 12 months of age) that serves similar nutritional purposes as any formulation of powdered infant formula covered by 21 U.S.C. § 350a(h)(1),

*except that such food shall not include Inventory Products defined in paragraph 7(E).*

This \_\_\_\_\_ day of May, 2022. \_

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HALA Y. JARBOU  
U.S. District Court Judge